

REMARKS

Following entry of the above amendments, claims 1-3, 7, 10-11, 14-33, 35-41, 47, 49, 52-54, 56, 58, 59, and 60 remain in the application for consideration. Claims 1, 7, 18, and 19 are herein amended. Claim 60 is newly added. Claims 4-6, 8-9, 12-13, 34, 42-46, 48, 50, 51, 55, and 57 are cancelled.

In the present response, claim 1 has been further limited to require the presence of at least three out of four specific substitution mutations in the protein Z sequence. Claims 8, 9, 12, and 13 which separately recited these mutations are cancelled.

New claim 60 has been added which recites the further limitation that all four mutations recited in claim 1 are present. Claim 18 has been amended to depend from new claim 60.

Finally, with the more precise definition of the binding polypeptide in claim 1, polypeptides comprising SEQ ID NO:5 are no longer within the scope of the claims, and as a result, claim 19 is amended accordingly.

No new matter is added by these amendments.

Rejections Moot or Withdrawn

Applicants note with appreciation the indication of mootness or withdrawal of previous rejections outlined in paragraphs 3-4 of the present office action.

Rejections Under 35 USC §102(b)

Claims 1-3, 7, 10-12, 14, 16, 17, 21-23, and 25 were rejected as being anticipated by WO 95/19374 to Nilsson et al. Applicants respectfully traverse the rejection.

Nilsson et al. disclose, among other things, a 58-residue polypeptide having at least four substitution mutations at positions 13, 14, 28, 32, and 35.

In contrast, the polypeptide recited in amended claim 1 comprises the amino acid sequence of Protein Z, having from 4 to 20 substitution mutations thereon at specific positions, and that those mutations comprise at least three of the following substitution mutations: (a) from phenylalanine to tyrosine at position 13, (b) from tyrosine to tryptophan at position 14, (c) from glutamine to arginine at position 32, and (d) from lysine to tyrosine at position 35. Applicants submit that the specific combination of mutations that are disclosed and particularly claimed in amended claim 1 are not disclosed or suggested by Nilsson et al., and therefore that the amended claims do not

anticipate Nilsson et al. Accordingly, Applicants submit that this rejection is overcome.

Moreover, Applicants submit that the invention as now claimed is not obvious in light of Nilsson et al. for the following reasons. Nilsson et al. disclose a general teaching regarding the usefulness of protein Z as a scaffold for the creation of binding molecules. However, this reference does not disclose any specific polypeptides capable of binding to HER2. Claim 1, as presently amended, is distinguishable from Nilsson et al., at least in that the polypeptide of amended claim 1 now comprises at least three of the four substitution mutations recited in the claim. The effect of these substitution mutations is binding capacity to HER2, as demonstrated by the fact that the sequences of all of the identified HER2-binding Z variants, except one, have this motif.

Applicants submit that there is no teaching or suggestion in Nilsson et al., or any of the other references of record, that would motivate one skilled in the art and faced with the HER2-binding problem to make any of the specific substitution mutations now recited in amended claim 1, or predict what the results would be. Accordingly, Applicants submit that the present invention is neither anticipated by or obvious over Nilsson et al., and that this rejection is now overcome.

Rejections Under 35 USC §112

Claims 8, 9, 13, 15, 18-20, 24, 25, 26-33, 35-41, 47, 49, 52-54, 56, 58, and 59 were rejected under 35 USC §112, Second Paragraph, as being indefinite by depending from rejected claims. Applicants submit that based on the present claim amendments outlined above, this rejection is now moot.

Applicants now submit that the claims are in condition for allowance, and respectfully request that a Notice of Allowance be issued.

If the Examiner has any questions concerning this application,
he is encouraged to contact the undersigned attorney.

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Respectfully submitted,

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